

REMARKS

Status of the Claims

Claims 36 to 54 are pending and under examination. Claims 46, 49 and 55 are under examination in the instant Office Action. Claim 48 has been cancelled. New claim 55 has been added. An equal number of claims has been cancelled (claim 48).

Claims 46 and 49 have been amended and claim 48 is cancelled without prejudice. Thus, after entry of the instant amendment, claims 46 and 49 and new claim 55 will be pending.

Support for the Claim Amendments

The specification sets forth an extensive description of the invention in the amended claims. Support for claims directed to a method involving the transient disruption of myelin or demyelination in neurological tissue can be found, inter alia, on page 17, lines 11-21; page 18, lines 8-10; page 27, line 13 and in the Examples on pages 30-50.

Applicants respectfully request entry of the amendments set forth in this response under 37 CFR §1.116. The amendment does not raise any issues of new matter and the amended claims do not present new issues requiring further consideration or search.

Rejections under 35 USC §112, first paragraph

Claims 46, 48 and 49 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly not enabling to a person skilled in the art to practice the invention commensurate in scope with these claims. In particular, the Examiner alleges that the instant specification does not enable the practice of the claimed method in any mammalian subject other than the rodent model exemplified in the specification. Applicants respectfully disagree with the Examiner's rejection.

Applicant has cancelled claim 48 without prejudice and has amended claim 46 to further clarify the subject matter of the invention. After entry of the instant amendment, the claims are directed to a method of treating a human by the transient disruption of myelin in neurological tissue as supported throughout the specification and particularly in the Examples.

Applicants respectfully traverse the foregoing rejection on the grounds that the claimed invention is fully enabled by the disclosure in Applicant's specification. Applicants submit that the Examiner's position, in effect, imposes an additional requirement, one not contained in 35 U.S.C. §112, of a working example or examples to enable the breadth of the claims directed to the claimed methods. Applicants assert that a working example is not required to enable the breadth of the pending claims and that "there is no magical relation between the number of representative examples and the breadth of the claims". In re Borkowski and VanVenroy, 164 U.S.P.Q. 642, 646 (C.C.P.A. 1970). In fact, § 112 only requires that the "specification contain a written description of the invention, and the manner and process of making and using it".

Additionally, it is well settled that the disclosure of invention set forth by Applicants in their application must be given the presumption of correctness and operativeness by the PTO, and the only relevant concern of the PTO under the circumstances should concern the truth of the assertions contained in the application. In re Marzocchi, 439 F.2d 220, 169 U.S.P.Q. 367 (C.C.P.A. 1967); see also, In re Bowen, 492 F.2d 859, 181 U.S.P.Q. 48 (C.C.P.A. 1974). The Examiner fails to proffer any evidence to controvert the truth of Applicants' assertions in the instant specification.

The Examiner bases the rejection on the assertion that the specification fails to provide any guidance on how to practice the method and therefore would require undue experimentation by a person skilled in the art. Applicants respectfully point out to the Examiner the teaching found, for example, at: pages 18-24 where the generation of antibodies for use in a human subject is described; pages 24-26 where the complement proteins or fragments for use in the invention are described; and pages 28-30 where teaching on the route, duration, and quantity for administration of this immunological activating composition is provided. In view of the teaching provided in the instant specification, it is asserted that the claimed method, as defined by the amended claims, would not require undue experimentation by the person skilled in the art and is, therefore, sufficiently enabled.

Applicants have amended claim 46 to recite a particular complement protein, C3 and has added a dependent claim, 55, to give an illustrative route of administration. Further, Applicants submit that the rat model shown in the examples is an acceptable model for human applications

In the Application of  
Steeves et al.

Application Serial No.: 09/530,234

Filed: July 6, 2000

Page 5

PATENT

Attorney Docket No.: MBM1200

of the invention. Further, Applicants have further defined the myelin epitope to which the antibody binds as Galactocerbroside (GalC), as exemplified in the working examples. Accordingly, Applicants respectfully request that the section 112 rejection be withdrawn.

**Rejections under 35 USC §112, second paragraph**

Claims 46, 48 and 49 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner asserts that claims 46, 48 and 49 are indefinite for being incomplete for omitting essential steps. The Examiner has asserted that the omitted steps are: the step that indicates the induction of myelin disruption, neuron regeneration, and treatment of nervous system dysfunction.

In making this rejection, the Examiner has referred to MPEP § 2172.01. It is our understanding that this rejection requires that the unclaimed matter must be described in the specification as being essential to the invention. Applicants respectfully point out to the Examiner that the instant invention relates to a method that involves the transient disruption of myelin and the resulting promotion of neuron repair. To promote neuron regeneration, in accordance with the invention, it is not necessary to carry out an indicating step as suggested by the Examiner. On page 17, lines 11-12, the specification defines "regeneration" as the regrowth of neurons that results in the reformation of neuronal connections, both anatomically and/or functionally." One of skill in the art will know of neuron specific markers, for example, that can be stained for on cells to determine whether there has been neuron regeneration. Alternatively, one of skill in the art can perform functional tests to determine whether there has been new neuronal cell growth in a tissue treated by the method of the invention (see experimental methods in Examples section of the specification). Moreover, nowhere is it described in the specification that the step of indicating regeneration is necessary to practice the invention. Accordingly, Applicants respectfully request withdrawal of this section 112 rejection.

In the Application of  
Steeves et al.

Application Serial No.: 09/530,234

Filed: July 6, 2000

Page 6

PATENT  
Attorney Docket No.: MBM1200

### CONCLUSION

In view of the foregoing amendment and remarks, it is believed that the Examiner should withdraw the rejection of the pending claims. Applicants believe all claims pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

The Commissioner is hereby authorized to charge any other fees that may be associated with this communication, or credit any overpayment to Deposit Account No. 50-1355. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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